

REMARKS

This is in response to the Official Action of May 16, 2003. Applicant has amended the claims to more clearly point out and distinctly claim the subject matter of the invention. In addition, certain typographical corrections have been effected to the specification. It is believed that the claims are now in a form which clearly distinguishes them from the prior art.

Briefly, the invention relates to discovery of a paste material which combines calcium containing powder and glycerol in a liquid form. The powder material converts to hydroxyapatite. The paste is useful as a bone or dental repair compound inasmuch as the paste has a very long shelf life and will not harden until exposed to water, for example, oral saliva. Thus the compounds comprising the paste of the invention may be premixed. Then when exposed to water the compound will convert into the bone replacement material, hydroxyapatite. By controlling the mixtures as taught in the patent, it is possible to control the timing for the conversion into hydroxyapatite. An essential feature of the invention is however, to make sure that the initial paste is water free. It is believed that this is an important and distinguishing feature relative to the prior art.

Referring to the prior art, in particular Constanz, U.S. Patent No. 5,962,028, it is noted that this patent utilizes a liquid including water. The fluidity is controlled by choice of various liquid materials that are added. Glycerol is usually present but in less than about 10% by volume. Constanz '028 discloses the use of water miscible pharmacologically acceptable liquids including glycerin in addition to the water. The liquid phase thus consists mostly of water with a small amount of organic liquid. The function of the additional liquid is to modify the fluid flow characteristics of the composition. The paste which is formed as taught in Constanz '028 is

capable of hardening in about 5-20 minutes after preparation. But it is formed or mixed just prior to use. It is not designed for shelf life.

In contrast the subject matter as set forth in the claims as amended teaches preparation of a premixed paste that is stable in the package for an indefinite period and hardens only after being delivered to the bone defect site where infusion of water from the surrounding tissue will initiate hardening. The premix formulation or paste as claimed is a water-free material and the presence of a small amount of water will render the premixed paste reactive and desirable for its intended purpose.

Constanz, U.S. Patent No. 5,782,971 again discloses the use of an aqueous lubricant for example, sterile water. The water used is substantially pure being doubled distilled, deionized or an equivalent thereof. Other materials are also added as liquid but less than 10% by volume. In any event the approach in Constanz '971 is to mix the liquid component and the powder component just prior to use. The utilization of water miscible materials such as ethylene glycol, propylene glycol or glycerol may find use in minor amounts in the context of the liquid or gel material that is added to the powder. Nonetheless, the component parts are kept separate until prior to use.

In contrast with the present invention, the liquid phase in the premixed paste interferes with the calcium mineral formation so that premixed paste will not react in the package. The glycerin and any other liquid used in place of glycerin is water free because only when they are water free will they inhibit cement setting. Thus the approach of the present invention is totally the opposite of Constanz which does not provide for a premixed material.

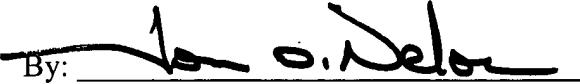
U.S. Patent No. 4,486,403 teaches the use of liquids in paste and mouth washes. The combination comprises primarily water and various other water-soluble constituents. All of the

disclosed combinations and materials in this patent contain water. In contrast to the premixed pasted of the present invention which is water free yet flowable and which is capable of shelf storage as a premix until it is exposed to water in the environment for which it is intended to be ultimately used as restoration or bone repair material.

In sum it is believed that the claims in their amended form are clearly distinguishable from the prior art for the reasons set forth above. Reconsideration thereof and passage to allowance is honestly solicited.

Respectfully submitted,

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